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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/578,935

05/09/2006

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0656-032US3A

5152

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12/11/2009

EXAMINER

GITOMER, RALPH J

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

12/11/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/578,935 | <b>Applicant(s)</b><br>SALTER ET AL. |  |
|                              | <b>Examiner</b><br>Ralph Gitomer     | <b>Art Unit</b><br>1657              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12, 14-17 and 24-79 is/are pending in the application.
- 4a) Of the above claim(s) 38-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12, 14-17 and 24-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

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The amendment received 11/18/09 has been entered and claims 1-10, 12, 14-17, 24-37 are considered here. Note in claim 1 line 5 "a one" may be a typo.

Newly submitted claims 67-79 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The newly added claims are directed to a method of preparing a test whereas the claims previously considered are directed to a test method of detecting antibiotics.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 67-79 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10, 12, 14-17, 24-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Markovsky in view of Charm.

Markovsky (6,319,466) entitled "Test Device for Detecting the presence of a Residue Analyte in a Sample" teaches in column 2 first full paragraph, the receptor may bind a family of analytes (one or a plurality of analytes) which have similar structural binding sites. Members of an analyte family can have different detection level requirements and, therefor, additional analyte binders can be employed, for example, monoclonal or polyclonal antibodies, that bind a portion of the analyte in competition with the receptor, in the sample, thereby decreasing test sensitivity. This adjusts the sensitivity for a specific analyte or group of analytes. The sensitivity of the test is adjusted so that a positive test result is not given unless a certain threshold of analyte is present in the sample. In column 5 lines 22-30 the sample is incubated at a higher than room temperature. In column 8 last paragraph the sensitivity to beta lactam is adjusted with the antibodies. In column 9 lines 27-42, the specific binding proteins, such as an

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enzyme, or monoclonal antibodies capable of binding to an analyte at a given concentration adjusts detection of one or more analytes to a specified level. Beta lactams are an example. In column 11 lines 25-40 a first binding can be for penicillin and a second binder for cloxacillin for example. Alternatively the first test zone can test for beta lactams and the second test zone can test for sulfonamides. In column 12 last full paragraph a purified beta lactam receptor from BST is discussed.

The claims differ from Markovsky in that the claimed method is based on a culture of spores where Markovsky does not grow organisms but based upon selective binding of the analyte.

Charm (4,239,745) entitled "Antibiotic Detection Method" teaches in the abstract, detecting antibiotics in milk by incubating the sample with antibiotic sensitive cells. In column 3 first paragraph the preferred microorganism for conducting assays for beta lactam antibiotics is BST. See the claims.

It would have been obvious to one of ordinary skill in the art at time of the invention to employ the assay taught by Charm and then adjust the sensitivity to the target antibiotic with the method of Markovsky in the same type of assay because Markovsky teaches the desirability of adjusting the sensitivity to any desired target antibiotic relative to another target antibiotic. And the utility of detecting multiple antibiotics at various concentration ranges or thresholds is shown by Markovsky.

Applicant's arguments filed 11/18/09 have been fully considered but they are not persuasive.

Applicants response argues that the references do not teach a sensitivity adjustment of a microbial growth inhibition test to one but not all of the families to which that test culture is sensitive. In the Declaration by Salter in paragraph 14 describes the invention as reducing sensitivity to beta-lactam antibiotics while increasing sensitivity to other antibiotics such as tetracyclines appropriate for the desired regulatory level determination. In the present specification on page 7 paragraph 33 a beta-lactam binder is used to adjust the sensitivity of the assay by reducing sensitivity to beta-lactams while test sensitivity to other antibiotics remains relatively unaffected to achieve sensitivity levels appropriate for different regulatory levels.

It is the examiner's position that the amended claims have been broadened where the method reads on detecting the presence of any single antibiotic only. None of the features argued are now found in the claims. Note that a Declaration does not substitute for a specification and the material in the Declaration cannot be added to the specification. The invention as described in the Declaration is inconsistent with the specification as originally filed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/  
Primary Examiner, Art Unit 1657

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Primary Examiner  
Art Unit 1657